



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

CERTIFIED MAIL;
RETURN RECEIPT REQUESTED AND VIA ELECTRONIC MAIL

Prakash Iyer
Senior Executive
Technology and Strategy Development
Inhance Technologies LLC
22008 N. Berwick Dr.
Houston, TX 77095

Re: Notice of Violation under the Toxic Substances Control Act

Dear Mr. Iyer:

The purpose of this letter is to notify you that the U.S. Environmental Protection Agency ("EPA") has determined Inhance Technologies LLC ("Inhance") was in violation of the long-chain perfluoroalkyl carboxylate ("LCPFAC") Significant New Use Rule ("SNUR"), 40 C.F.R. § 721.10536, promulgated under the Toxic Substances Control Act ("TSCA"). On January 14, 2021, we sent you an Information Request under Section 11 of TSCA, 15 U.S.C. § 2610, regarding the manufacture, processing, or use of fluorinated HDPE containers. In March 2021, the EPA tested several high-density polyethylene ("HDPE") containers manufactured, processed, or used by your company and detected several LCPFAC substances subject to the SNUR in the rinsates from the HDPE containers.¹

We have reviewed the results of the EPA's analysis of the LCPFAC substances detected in your products along with the information you submitted in your February 1 and 8, 2021 responses to the EPA's Information Request. Based on this review, the EPA has determined that Inhance's manufacture of several LCPFAC substances² produced during the fluorination of HDPE containers is a significant new use under the LCPFAC SNUR. Specifically, the EPA has determined that regulated LCPFAC substances are produced as a byproduct during the fluorination process and do not have a separate commercial intent.

The manufacture of certain LCPFAC substances, as defined in the LCPFAC SNUR, 40 C.F.R. § 721.10536(b), for any use is a significant new use of those LCPFAC substances under the

¹ See Memorandum from Thuy Nguyen to Kimberly Nesci (March 4, 2021), *available at* https://www.epa.gov/sites/default/files/2021-03/documents/results-of-rinsates-samples_03042021.pdf.

² Specifically, the following LCPFAC substances manufactured by Inhance are subject to the SNUR: Perfluoro-octanoic acid ("PFOA"); Perfluoro-nananoic acid ("PFNA"); Perfluoro-decanoic acid ("PFDA"); and Perfluoro-undecanoic acid ("PFUDA").

SNUR. 40 C.F.R. § 721.10536(b)(4)(iv). Persons who intend to engage in a significant new use of a chemical substance are required to submit a Significant New Use Notice (“SNUN”) under 40 C.F.R. §§ 721.5 and 721.25 at least 90 days before commencing the manufacture (including import) or processing of subject chemical substances for this significant new use. Additionally, the EPA must conduct a review of the SNUN, and issue a determination on the SNUN, and take any actions required in association with that determination pursuant to Section 5(a)(1)(B) of TSCA, 15 U.S.C. § 2604(a)(1)(B).

Byproducts are exempt from the requirements of 40 C.F.R. Part 721 when they are used only by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes. 40 C.F.R. § 721.45(e). Our review of the information you submitted on the use of the fluorinated HDPE containers does not support the position that the manufactured LCPFAC substances fall under one of these three uses, and thus the significant new use is not exempt from the notice requirements as a byproduct.

In your February 8, 2021 response to our Information Request, you asserted that the presence of LCPFAC substances are impurities of the process of fluorinating the HDPE containers. The EPA’s review of the information you submitted in response to the Information Request and the results of the EPA’s March 2021 analysis of LCPFAC substances in Inhance’s containers does not support the position that the LCPFAC substances detected are impurities. An impurity is a substance that is introduced unintentionally as part of one of the raw materials used as an input to a process that remains unreacted.³ The information you submitted indicates that the LCPFAC substances detected in the fluorinated containers were manufactured during the fluorination process. Because the LCPFAC substances were manufactured during the fluorination process rather than present as an input to the fluorination process, the LCPFAC substances are not impurities under 40 C.F.R. Part 721.⁴

Pursuant to Section 15 of TSCA, 15 U.S.C. § 2614, failure to comply with any requirement of this title or any rule promulgated pursuant thereto are prohibited acts under TSCA. By way of this letter, we provide Inhance an opportunity to provide additional information to the EPA with respect to its fluorination of HDPE containers. If Inhance has ceased the manufacture of LCPFAC substances subject to the SNUR, please provide the EPA with documentation that:

- 1) explains the changes in process for the fluorination of HDPE containers; and
- 2) confirms how these changes in process ceased the manufacture of LCPFAC substances subject to the SNUR.

If Inhance has not changed its process to prevent the manufacture of LCPFAC substances, in order to return to compliance, Inhance must immediately cease the manufacture of LCPFAC substances subject to the SNUR. Prior to resuming manufacture, Inhance must submit a SNUN

³ Additional information on distinguishing byproducts from impurities is available at <https://www.epa.gov/chemical-data-reporting/determining-chemical-substances-subject-cdr-rule>.


⁴ Although there was some PFOA present in the untreated containers tested by EPA which may constitute an impurity, the levels of PFOA detected after the fluorination treatment supports that the fluorination process manufactured additional PFOA.

to the EPA and receive an EPA determination on that SNUN. Please provide the above information on Inhance's change in process for the fluorination of HDPE containers or its notification that it has ceased operations that result in the manufacture of LCPFAC substances subject to the SNUR to Lindsay Simmons (Simmons.Lindsay@epa.gov) within 30 days of receipt of this letter.

If you have any other questions about the substance of this request, please contact Lindsay Simmons at the aforementioned email address or 202-564-3223. Thank you for your cooperation and prompt attention to this matter.

Sincerely,

**JAMES
MILES**

 Digitally signed by
JAMES MILES
Date: 2022.03.01
09:02:42 -05'00'

James Miles
Chemical Risk and Reporting Enforcement Branch Chief
Waste and Chemical Enforcement Division
Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency

cc: Dorothy E. Watson, Counsel to Inhance Technologies LLC